

K 964117

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1. SUBMITTER

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2. NAME OF DEVICE: KAWASUMI LABORATORIES NON-PVC FLUID PATH PORT
ACCESS INFUSION SET WITH SLIT SEPTUM INJECTION SITE

COMMON NAME: WINGED ACCESS SET

CLASSIFICATION: UNCLASSIFIED

3. PREDICATE DEVICE: KAWASUMI LABORATORIES PORT ACCESS INFUSION SET
AND BAXTER HEALTH CARE'S "INTERLINK" SLIT SEPTUM
INJECTION SITE.

4. DESCRIPTION OF THE DEVICE: A NON-PVC PORT ACCESS INFUSION SET IS A
STERILE, SINGLE USE DEVICE WITH A NEEDLE, WING, NON-
PVC I.D. TUBING AND NON-PVC COMPONENTS USED FOR
ACCESSING IMPLANTED MEDICATION PORTS.

BASIC CONCEPT: A DEVICE USED FOR ACCESSING AN IMPLANTED
MEDICATION PORT BY PUNCTURING THE SEPTUM
OF THE MEDICATION PORT USED FOR THE DELIVERY
OF MEDICATION. FLUID ADMINISTRATION
THROUGH THE NON-PVC FLUID PATH PORT ACCESS
INFUSION SET ARE THOSE GENERALLY USED IN HOSPITALS
AND FOR CHEMOTHERAPY.

SIGNIFICANT PERFORMANCE CHARACTERISTICS: THERE ARE NO NEW
PERFORMANCE CHARACTERISTICS OF THIS DEVICE
COMPARED TO SUBSTANTIALLY EQUIVALENT DEVICES
MARKETED FOR SALE IN INTERSTATE COMMERCE. BOTH
DELIVER FLUID TO THE VASCULAR SYSTEM THROUGH A
NON-REACTIVE MATERIAL.

5. INTENDED USE: THE NON-PVC PORT ACCESS INFUSION SET IS
ROUTINELY USED TO ACCESS IMPLANTED MEDICATION
PORTS FOR THE DELIVERY OF MEDICATIONS.

6. TECHNOLOGICAL CHARACTERISTICS: THERE ARE NO TECHNOLOGICAL
CHARACTERISTICS OF THIS DEVICE TO SUBSTANTIALLY
EQUIVALENT DEVICES INCLUDING KAWASUMI AND
BAXTER SETS BEING MARKETING FOR SALE IN
INTERSTATE COMMERCE. THIS DEVICE USES A
COEXTRUDED TUBE WHICH DOES NOT EXPOSE THE
FLUID DELIVERED INTRAVASCULARLY TO PVC.

7. PERFORMANCE DATA: KAWASUMI LABORATORIES HAS CONDUCTED BIOCOMPATIBILITY TESTS ON THE BODY FLUID CONTACTING MATERIAL PORTIONS OF THE DEVICE, AND KL BELIEVES THE BIOCOMPATIBILITY DATA SHOW THE DEVICE IS SUITABLE FOR ITS INTENDED USE.

THE DEVICE MEETS THE LIMULUS AMEBOCYTE LYSATE ("LAL") TEST DESCRIBED AT "(85) BACTERIAL ENDOTOXINS TEST", USP XXII, PP 1493-1495.

8. CONCLUSIONS: THE DEVICE MEETS ALL BIOCOMPATIBILITY AND PYROGENICITY TEST REQUIREMENTS. THEREFORE, IT IS AS SAFE AS THE PREDICATE DEVICE AND PERFORMS AS WELL AS THE PREDICATE DEVICE.